Medivir

A collaborative and agile pharmaceutical company with an R&D focus on infectious diseases and a leading position in hepatitis C

Nordea lunch

24 January 2013

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Value proposition

Collaborative and innovative pharmaceutical company

- World class expertise in polymerase and protease drug targets
- R&D focus on infectious diseases

Strong position in HCV – both partnered and internal programs

- Simeprevir (TMC435), considered “best in class HCV protease inhibitor”
  - partnered with Janssen Pharmaceuticals with retained Nordic rights
  - regulatory filing in H1 2013 as triple combination treatment with PegIFN/ribavirin
  - optimal profile for future interferon-free combination treatments
- In-house HCV programs will offer combination opportunities

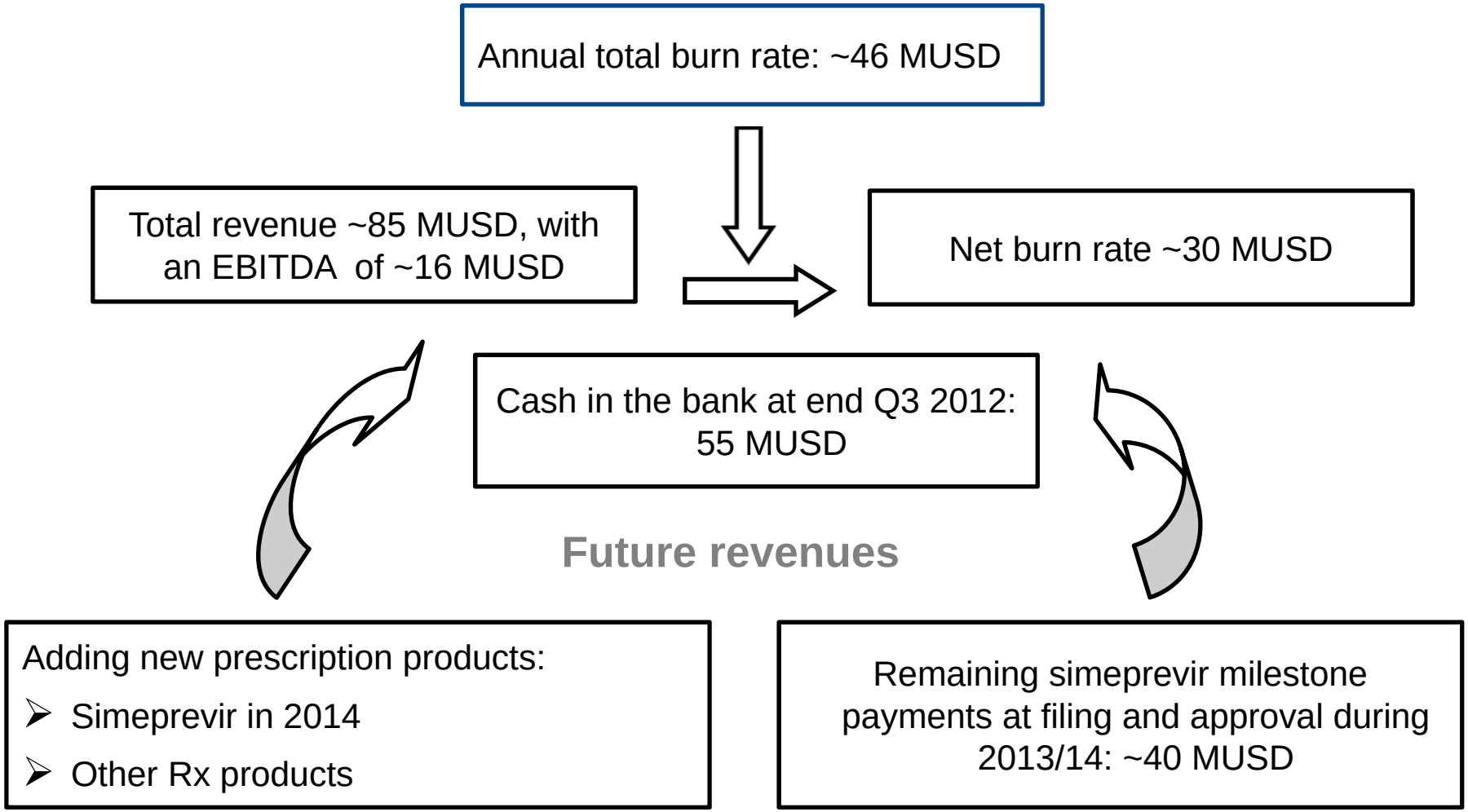
BioPhausia – a Medivir sales company

Commercial presence in the Nordic region

- Solid brand names, annual sales of ~85 MUSD
- New pharmaceuticals will be added
- Commercial platform for the launch of simeprevir in the Nordics in 2014

Stable financial position -

Commercial presence in the Nordics plays an important role for financing R&D



Strategic direction and ongoing activities

R&D Operations

Further development of R&D platform

- Continued focus on HCV and infectious diseases
- Evaluate new therapeutic areas based on proteases and polymerases as drug targets

Create new partnership/collaborations

- Continue to develop R&D assets via partnerships

Commercial Operations

Expand commercially

- Add new products for the Nordic market
- Build organisation for Nordic launch of simeprevir
- Further development of business and therapy scope

Medivir in a 3-5 year perspective

Structure

- Partner of choice for both pharmaceuticals and development programs
- Continued commitment on targets in infectious diseases
- Adressing of new therapeutic areas based on core competence
- Aggressive expansion of product portfolio, including simeprevir and other in-house developed pharmaceuticals
- Broader, risk balanced, R&D pipeline

External perspective

- Top ranked as a listed company
- Profitable and fast growing Nordic pharmaceutical company

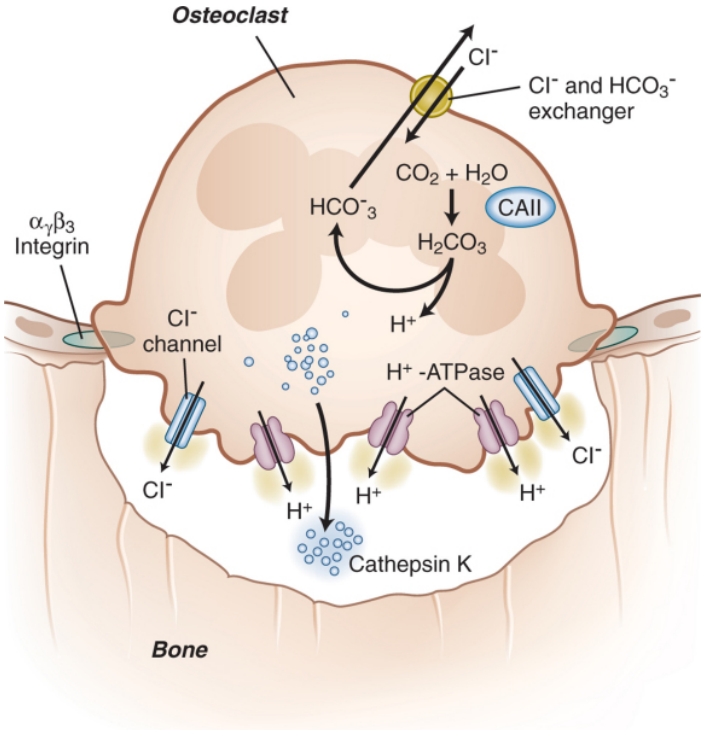
R & D

A focused project portfolio

Therapeutic area	Product/Project	Partner
ANTIVIRALS		
Labial herpes	Xerclear® (Zoviduo, Zovirax Duo)	GlaxoSmithKline (GSK)
Hepatitis C	Simeprevir (TMC435), NS3 protease inhibitor	Janssen Pharmaceuticals
	NS5B nucleotide polymerase inhibitor	Janssen Pharmaceuticals
	NS5B nucleotide polymerase inhibitor	
	NS5A replication complex inhibitor	
Hepatitis B	Lagociclovir valactate (MIV-210)	Daewoong
Dengue fever	NS3 protease inhibitor	Janssen R&D Ireland
HIV	Protease inhibitor	Janssen Pharmaceuticals
OTHER INDICATIONS		
Bone related disorders	Cathepsin K inhibitor	
Neuropathic pain	Cathepsin S inhibitor	

Cathepsin K inhibitors - mechanism of action

Osteoporosis/osteoarthritis/metastatic bone disease



Osteoporosis and osteoarthirits

- cathepsin K dissolves collagen I in bone and collagen II in cartilage
- genetic, animal and human data shows that cat K inhibition improves bone quality

Metastatic bone disease

- invasive tumour cells express high levels of cathepsin K, which increase bone resorption and the invasiveness of cancer cells

Recent data suggest that cat K inhibitor reduces fracture risk in humans

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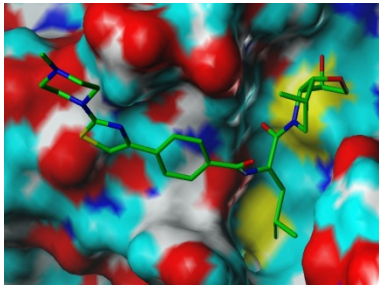
Cathepsin K inhibitor
- a phase I clinical program



Disease

Osteoporosis, osteoarthritis and metastatic bone disease

MIV-711: Phase I clinical trial ongoing

- Adaptive, placebo controlled, double-blind study in healthy volunteers incl. post meno-pausal women
- Ascending single and multiple (7 - 28 days) once daily dosing
- Biomarkers for bone and cartilage turnover

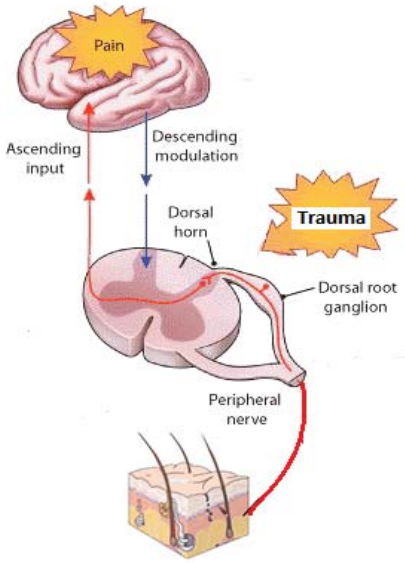
- Phase I completed and data available H1-2013

MIV-711 - a phase I clinical candidate efficacious on bone and cartilage biomarkers in osteoarthritis and osteoporosis models

Cathepsin S inhibitor – neuropathic pain and rheumatoid arthritis

Principle for neuropathic pain (NP)

- Associated with a lesion or disease affecting the somatosensory system
- Includes e.g. diabetic neuropathic pain, post-herpetic neuralgia & neuropathic lower back pain



Medical need and market

- Current treatments incl. anticonvulsants and antidepressants
  - Pain persists in 75% patients with at best a 50% reduction in overall pain
  - Significant side effects e.g. dizziness, somnolence
- 25M people in the 7 MM suffer from NP

Mechanism of action:

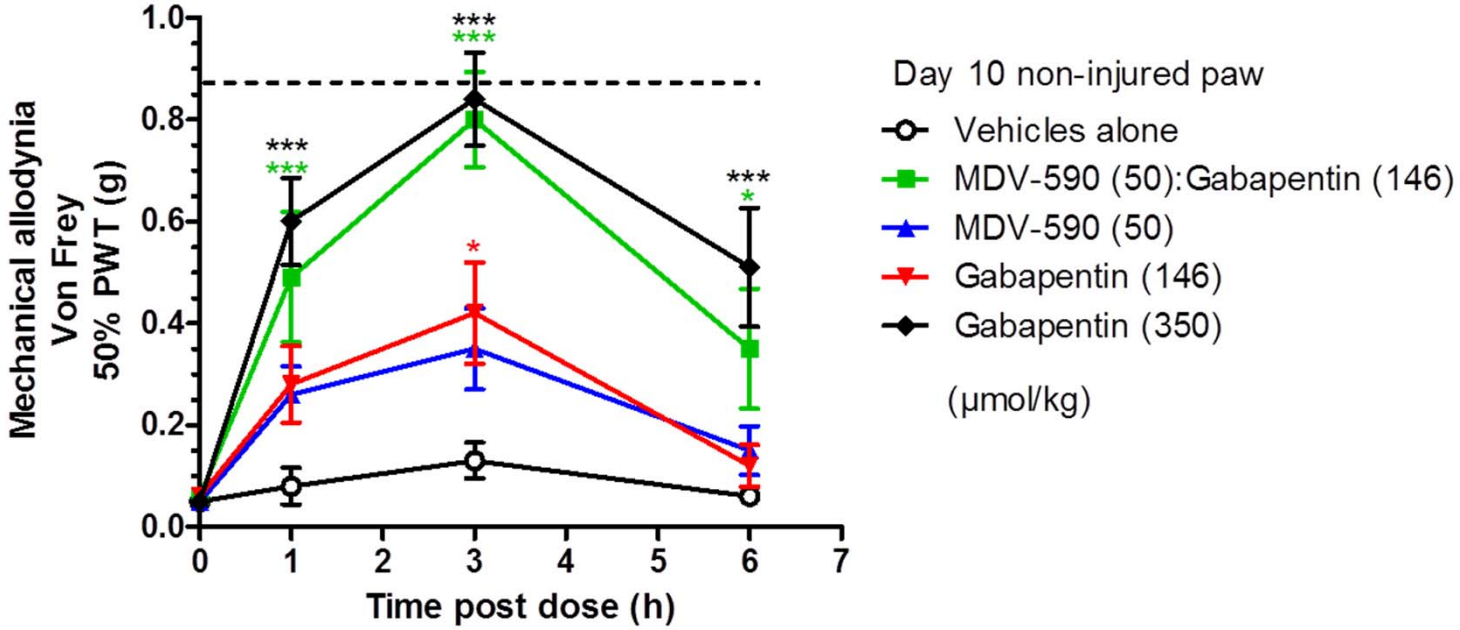
- Inhibition of Cathepsin S prevents inflammatory damage to the sensory system in the spinal cord by blocking fractalkine activation

Cathepsin S inhibitor program

- Potent, selective and orally bioavailable inhibitors available
- Aiming for candidate drug selection in Q1 2013

Cathepsin S inhibition – a novel mechanism for pain releaf

Combining minimal effective doses of a cathepsin S inhibitor (MDV-590) and gabapentin in a neuropathic pain model leads to synergistic effects



Cathepsin S inihibition is efficacious as monotherapy and is synergisiic with gabapentin in a neuropathic pain model

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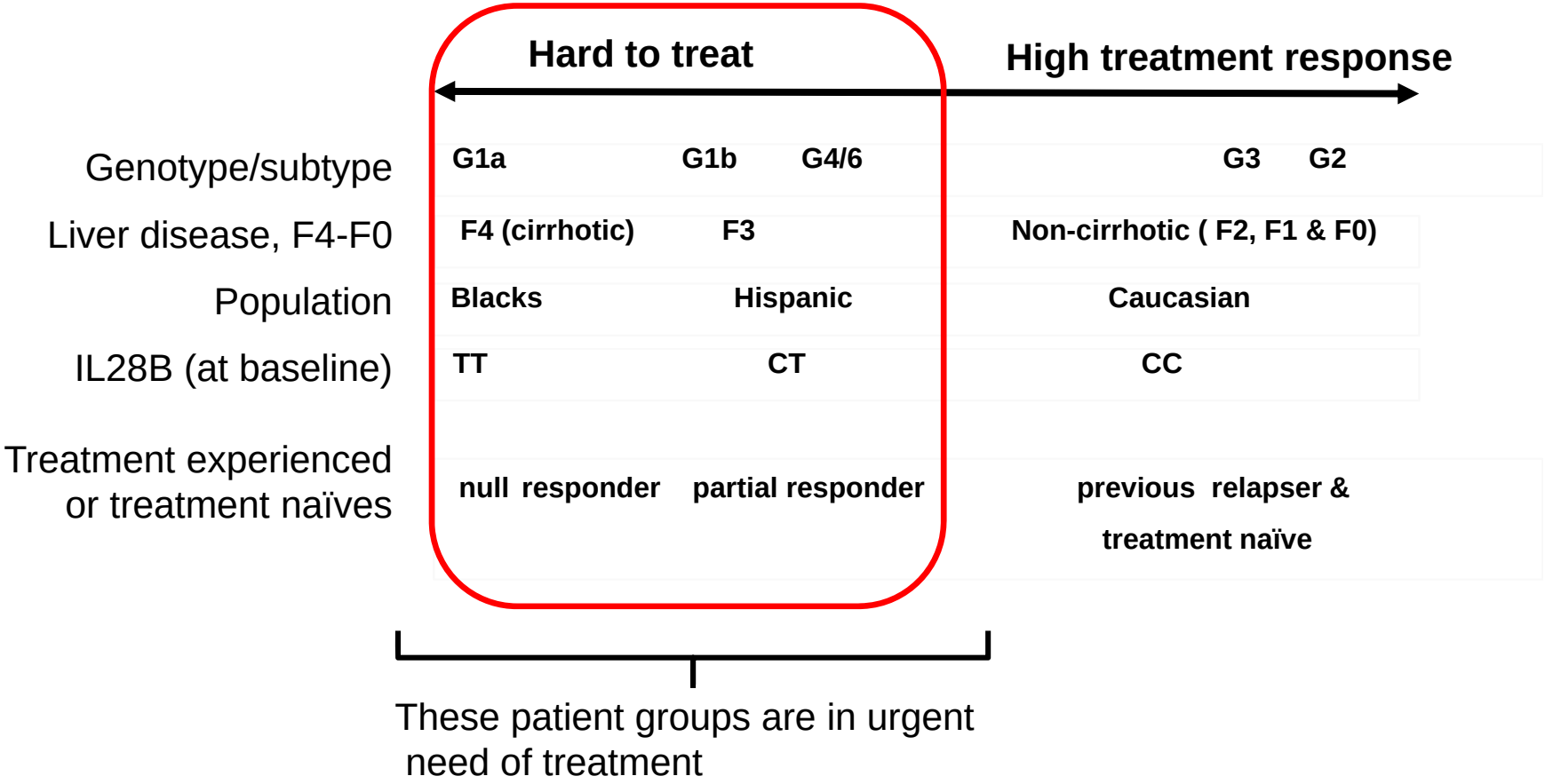
Simeprevir (TMC435) soon to reach the market in a rapidly evolving treatment landscape

Patient response to treatment – a complex picture



Simeprevir has demonstrated efficacy in difficult to treat GT1 patients with severe liver disease

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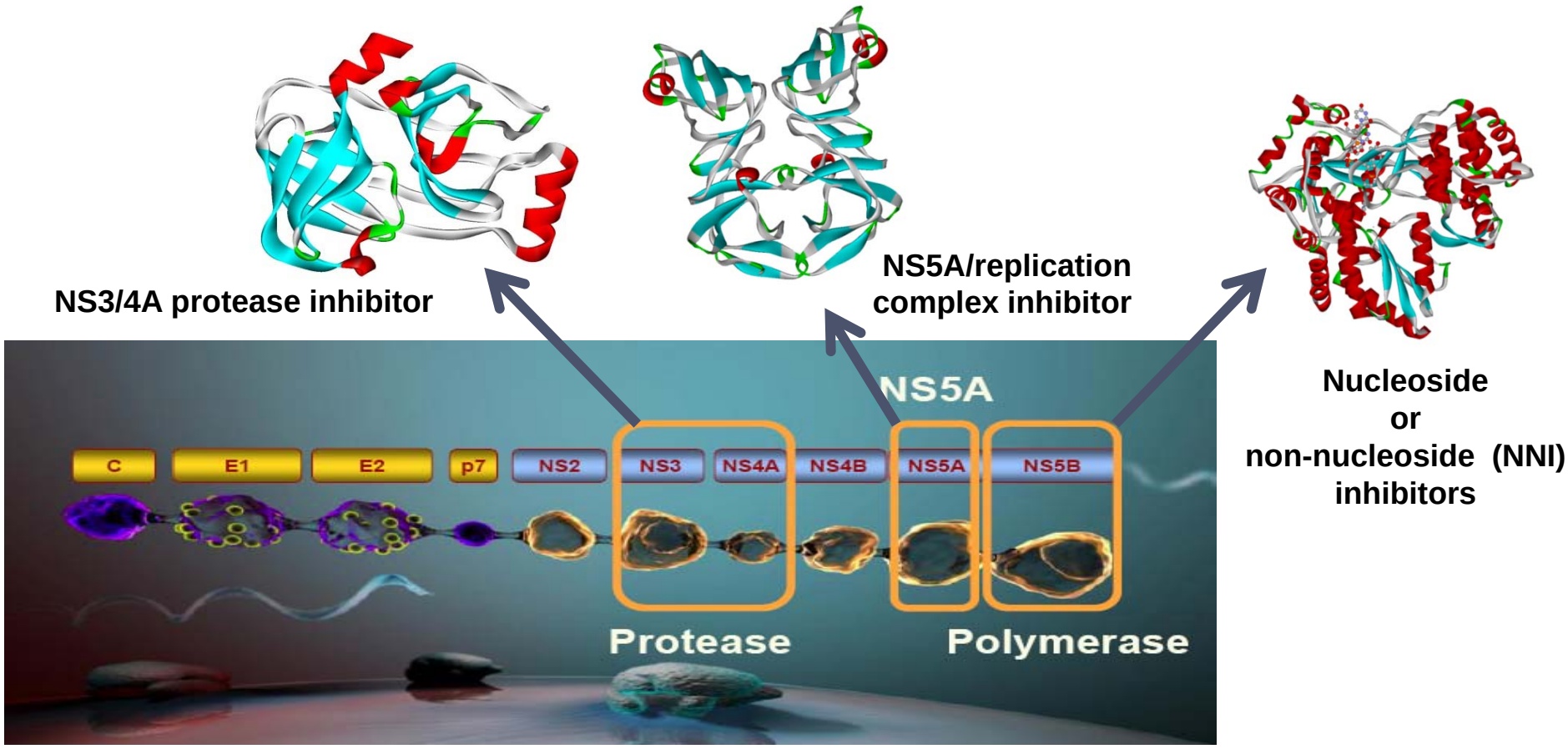
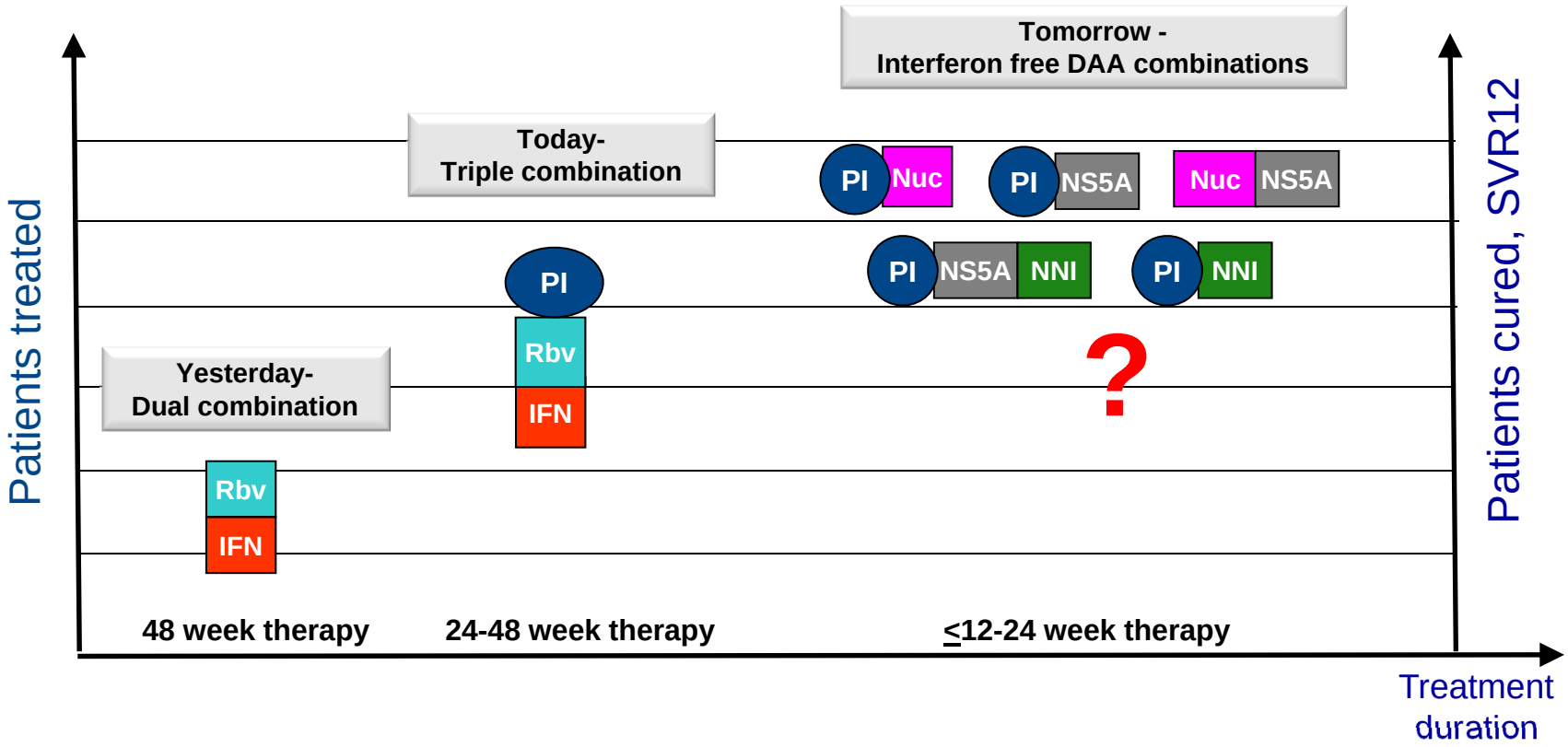
Strong commitment in hepatitis C
– four major programs versus the three major targets



Simeprevir – An efficacious, safe and tolerable protease inhibitor*

*as demonstrated in 3 pivotal phase III studies in GT1 HCV infected naive and relapser patients

Evolution of HCV therapy in HCV G1 infection



Simeprevir

✓a safe and tolerable 2nd generation protease inhibitor based on phase III

✓well positioned for triple as well as future interferon free combination therapies

Simeprevir (TMC435), clinical development programs in HCV G1 & 4 infected patients

Pivotal phase III studies:

- **QUEST 1** treatment-naïve
- **Quest 2** treatment-naïve
- **PROMISE** prior relapsed
- **Japan** naïve & experienced (four studies)

Other ongoing phase III studies:

- **China:** Efficacy, PK, safety and tolerability in naïve patients
- **ATTAIN:** Simeprevir vs telaprevir in prior null or partial responders
- **HCV genotype 4 infected** naïve or treatment experienced patients
- **HIV** co-infected patients

Regulatory filings for triple combination in first half of 2013 in US, EU & Japan

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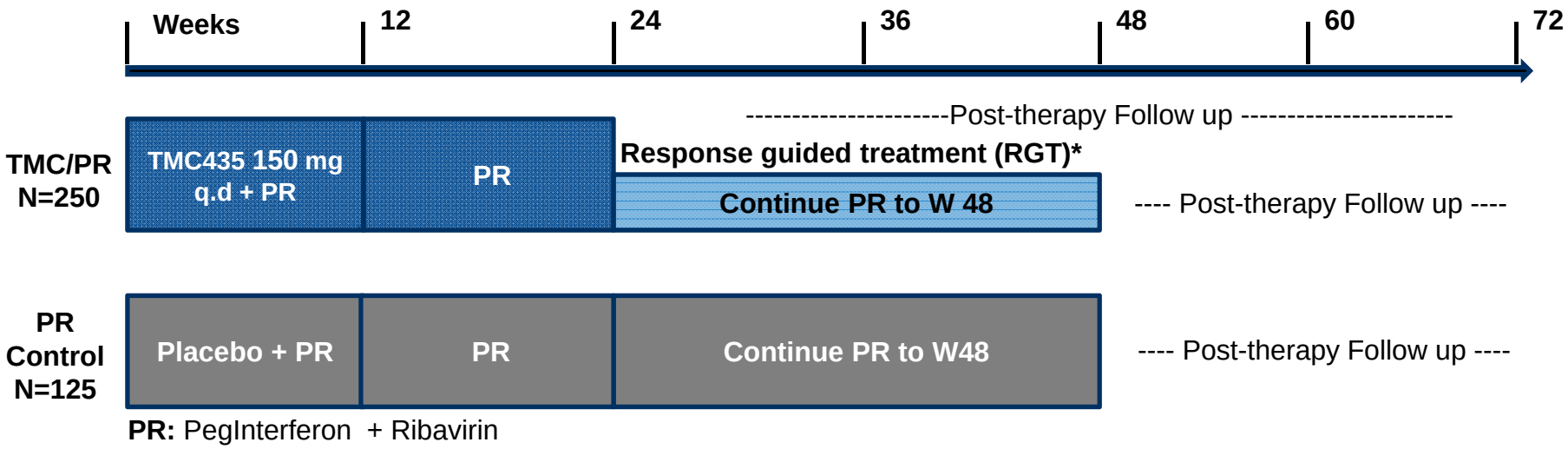
For additional information, please see www.clinicaltrials.gov

Simeprevir - Phase III Study designs in HCV GT1 infected patients

Response guided, double-blind, placebo controlled

2:1 randomization



PR: PegInterferon + Ribavirin

Studies:

QUEST-1: n=394, naive (METAVIR score F3-F4: 30%)

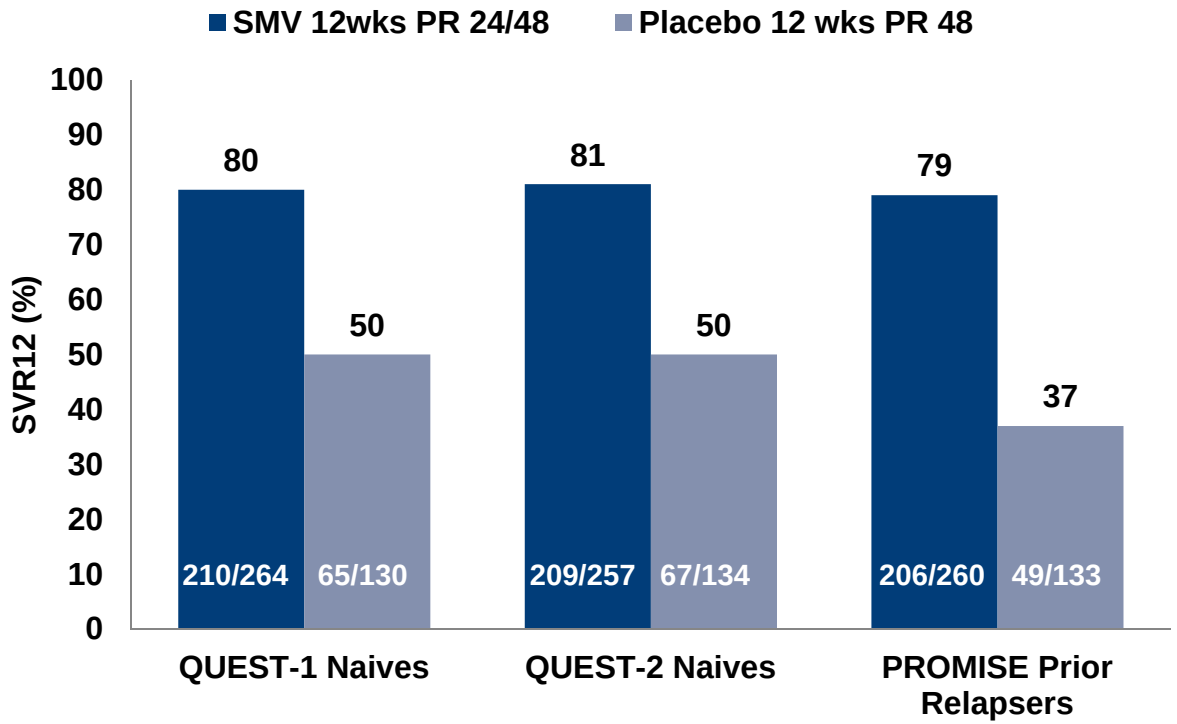
QUEST-2: n=391, naive, (METAVIR score F3-F4: 22%)

PROMISE: n=393, prior relapsers, (METAVIR score F3-F4: 31%)

*HCV RNA < 25 IU/mL (detectable or undetectable) at Week 4 and undetectable (< 25 IU/mL undetectable) at Week 12

Simeprevir - Phase III Triple therapy

Efficacy – SVR12 (cure rate)



Statistically significant difference vs placebo control in all studies

Robust efficacy in all three studies (79-81% SVR12) - confirming phase II studies

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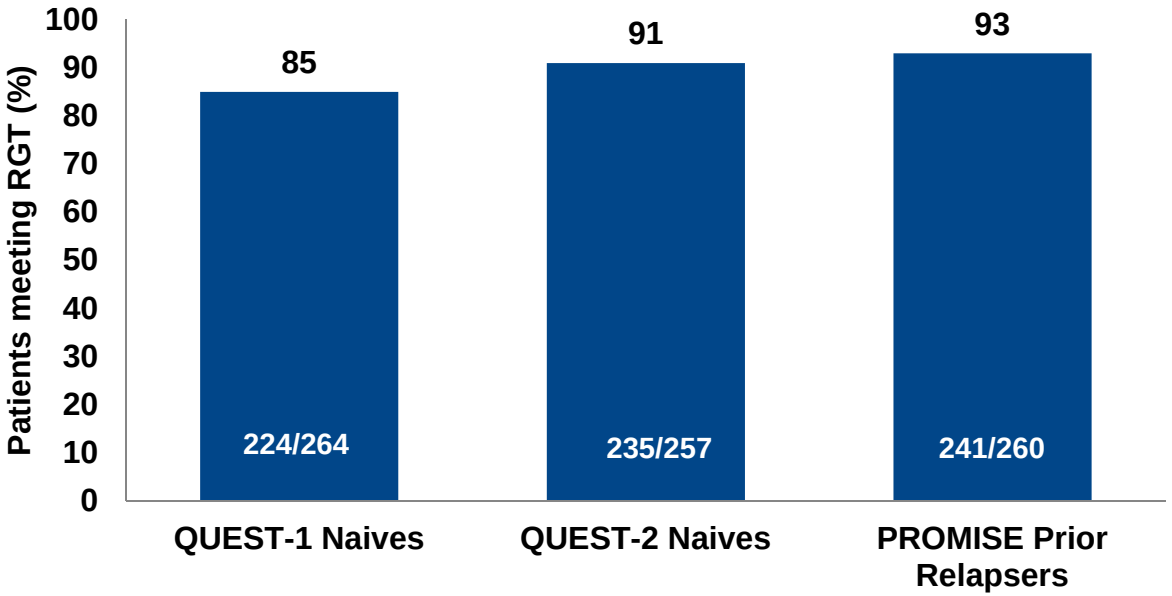
Simeprevir - Phase III Triple therapy

Efficacy – Response Guided Treatment (RGT)



Markedly shortened treatment durations:
85 - 93 % of the patients were able to stop all treatment at week 24

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Simeprevir - Phase III triple therapy

Results – Safety and Tolerability

- Overall simeprevir was safe and well tolerated
  - ✓ Incidence of adverse events, including rash and anemia, were similar to those observed in the placebo control group
- Mild and reversible increases in bilirubin were observed in simeprevir dose groups
- Discontinuations due to AEs were consistently lower in the simeprevir treatment arms as compared to control

Overall incidence of adverse events was similar to placebo control

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Simeprevir - Phase III triple therapy

Summary

- **Robust efficacy** - high cure rates in all trials (SVR12 in 79, 80 and 81%)*
- **Excellent safety and tolerability** - incidence of adverse events, including rash and anemia, similar to placebo

Phase III data support simeprevir as a new treatment for G1 HCV, with advantages vs marketed 1st generation PIs is:

Safer – similar AE profile as placebo (vs known issues with 1st generation PIs)

Shorter – 85-93 % could stop all treatment at week 24 (vs ≤ 60%)

Simpler – 1 pill, once daily (vs. 2-3 times daily)

Regulatory filings for simeprevir triple combination H1- 2013 in US, EU & Japan

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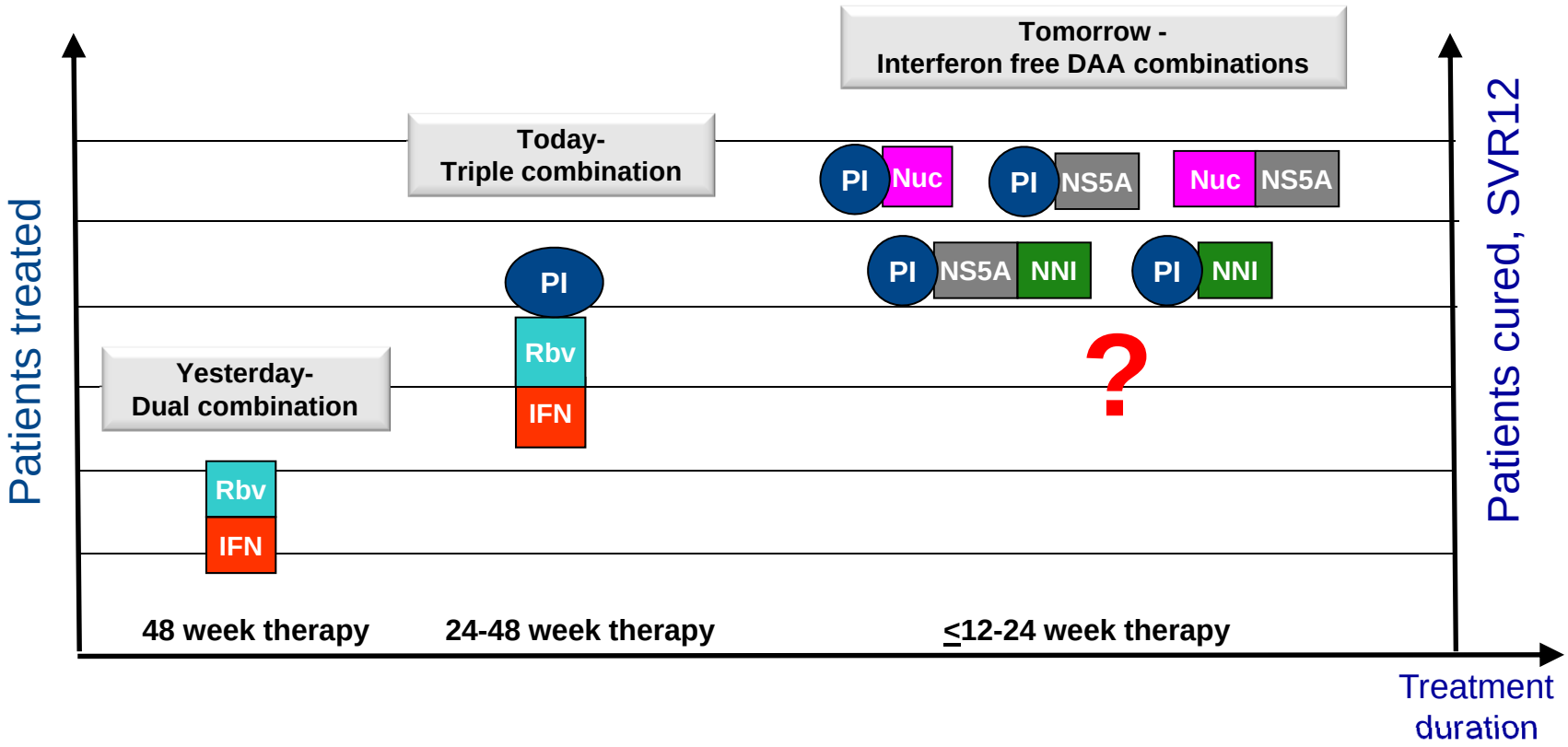
* All three trials included difficult-to-treat patients with advanced liver fibrosis/cirrhosis (METAVIR score F3-F4)

Evolution of HCV therapy in HCV G1 infection

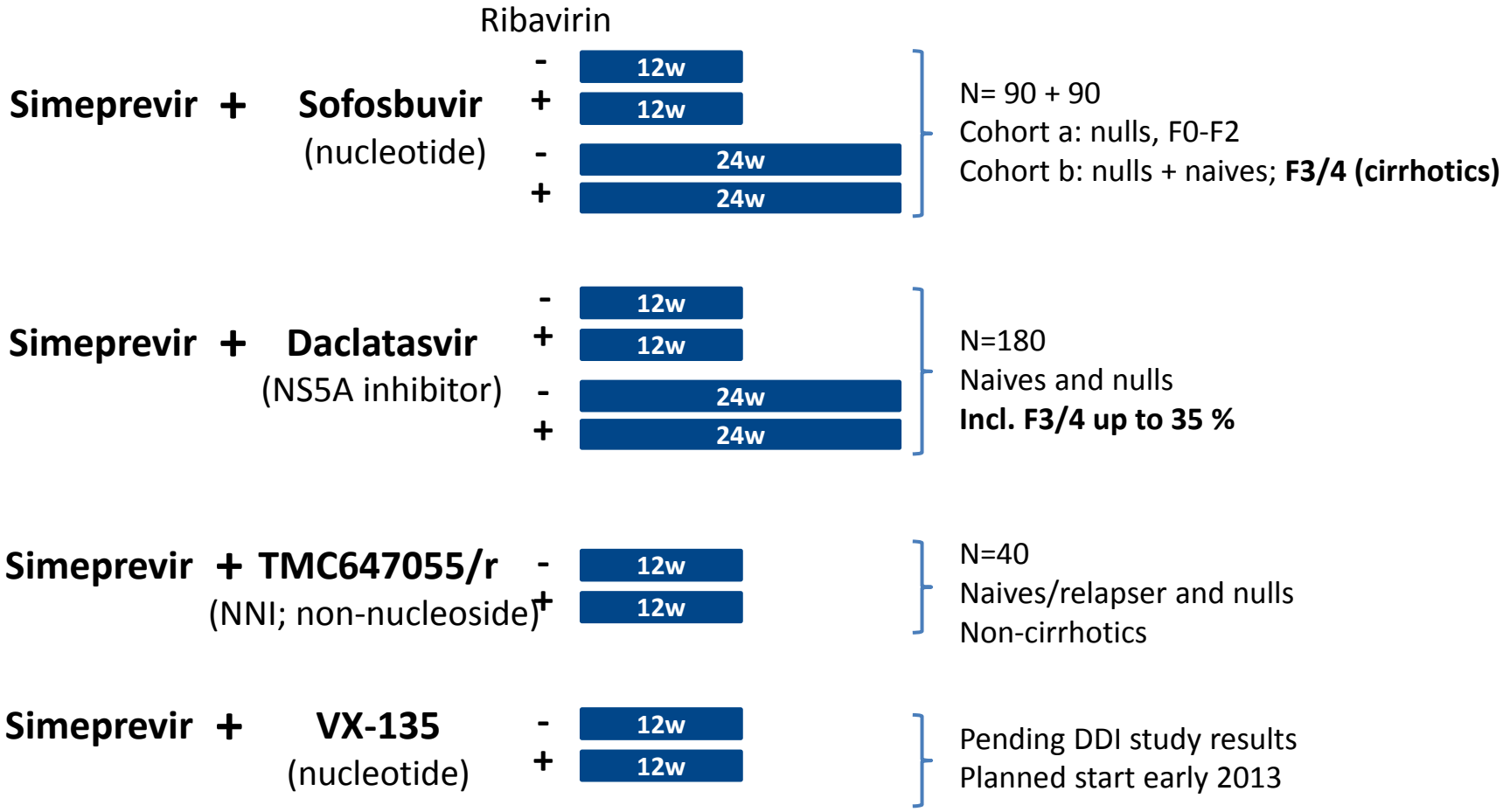


Simeprevir

✓a safe and tolerable 2nd generation protease inhibitor based on phase III

✓well positioned for triple as well as future interferon free combination therapies

Simeprevir (TMC435) – interferon free combinations



Simeprevir - strongly positioned to become a principal component of future IFN-free therapies

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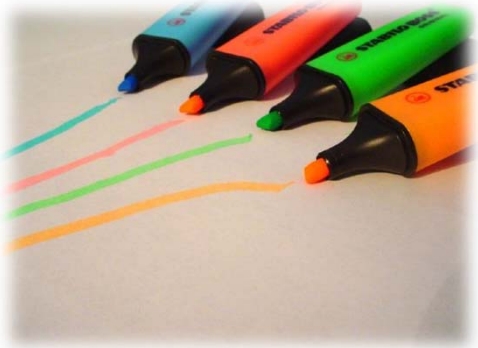
For additional information, please see www.clinicaltrials.gov

Strong news flow - highlights



- ✓ Q3-12 Start of Phase Ib clinical trials with MIV-711, a cathepsin K inhibitor
- ✓ Q4-12 Start of Cohort 2 with simeprevir and GS7977 phase II study
- ✓ Q4-12 Top line results from phase III trials with simeprevir (Quest 1+2 and Promise)
- Q1-13 Potential CD selection in Cathepsin S (neuropathic pain) program
- Q1-13 EoT and partial SVR data from Cohort 1 with simeprevir and GS7977 phase II study
- H1-13 Results from the phase I-study with MIV-711 (bone related disorders)
- H1-13 Start of phase II study with simeprevir and VX-135
- H1-13 Expected CD selection in our internal Nucleotide NS5B inhibitor program
- H1-13 Goal to start phase 1 trials with Medivir/Janssen nucleotide NS5B-inhibitor
- H1-13 EoT-data from the phase II combination study with simeprevir and daclatasvir
- H1-13 Filing of simeprevir in US/EU and Japan
- H1-13 Step two in GSK launch strategy for Xerclear® (ZoviDuo), launch in major European OTC markets

www.medivir.com

Ticker: MVIR
Exchange: OMX / NASDAQ

For more info please contact
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Appendix

Simeprevir, triple combination therapy with PegINF/RBV
- summary phase IIb efficacy data

Study	Total no. of patients	Patient population	SVR24 (%)	SVR24 P/R control (%)	Delta
Pillar	**386**	**Treatment naive**	**83**	65	18
Dragon	**92**	**Treatment naive (JPN)**	**82**	46	36
Aspire	**462**	**Treatment experienced**	**73**	23	50

Prior response to PegINF/RBV	SVR24 (%)	SVR24 P/R control (%)
Relapser	**85**	37
Partial responders	**76**	9
Null responders	**51**	19

Safe and efficacious with excellent tolerability, one pill once daily

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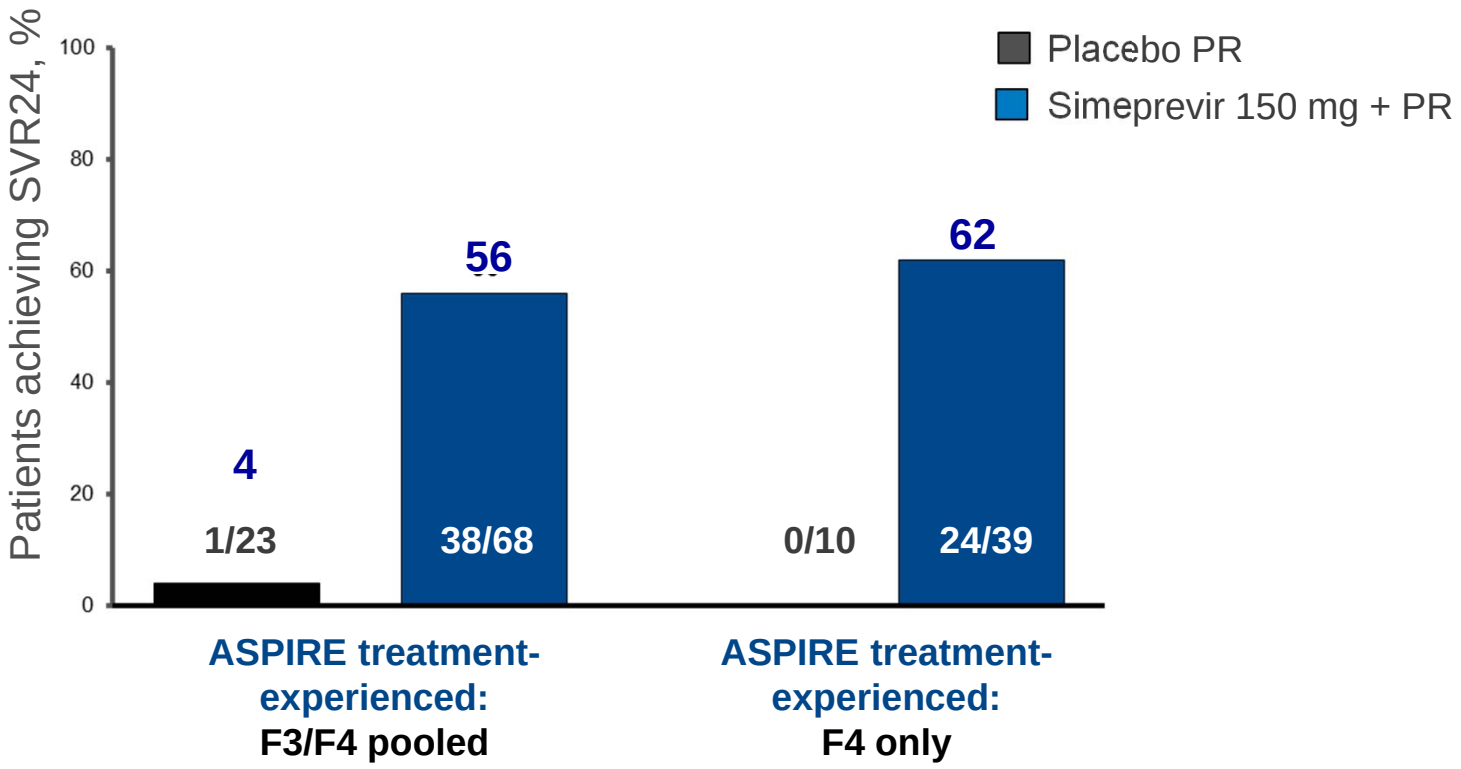
ASPIRE
– a phase II study in treatment-experienced G1 HCV patients



High SVR rates in patients with advanced liver disease (F3 and F4)

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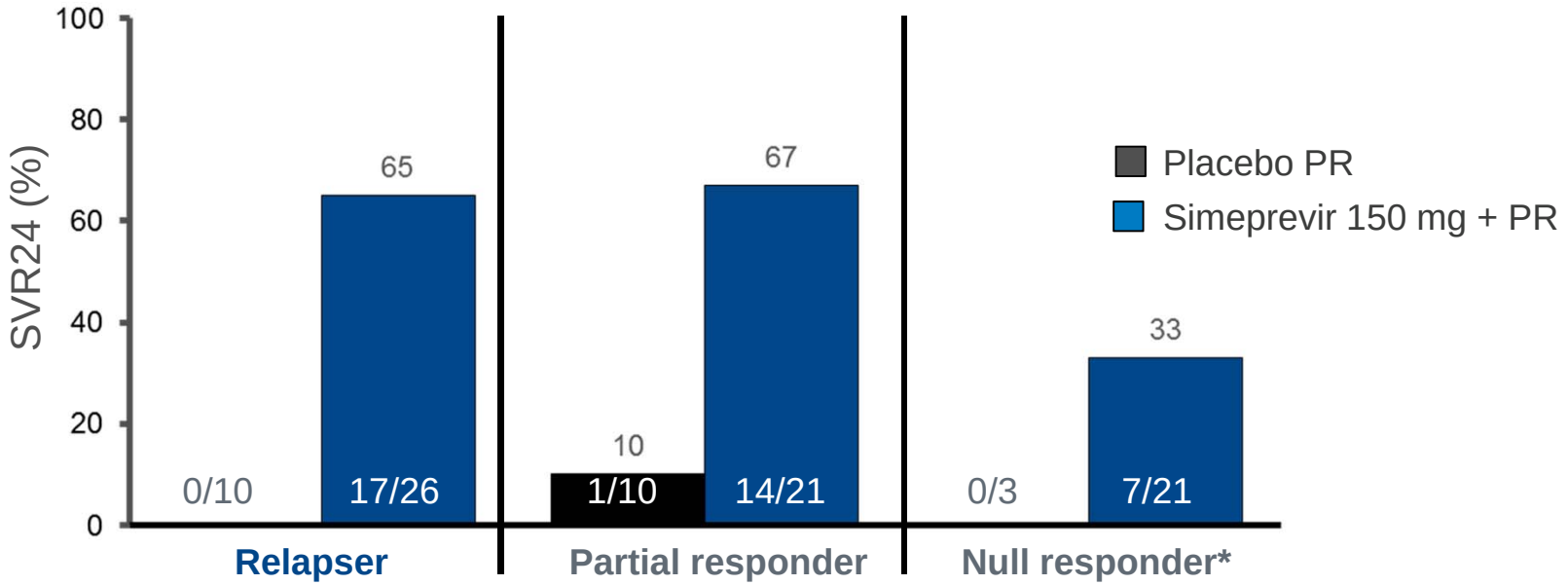
*Treatment arms within ASPIRE with different durations pooled
PR, pegylated interferon α-2a + ribavirin; SVR24, HCV RNA <25 IU/mL undetectable 24 weeks after planned end of treatment

ASPIRE
– a phase II study in treatment-experienced G1 HCV patients

SVR24 by prior response to PegIFN/RBV in F3/F4 patients



*** 31% (4/13) null responders with cirrhosis (F4) achieved SVR24**

Simeprevir was safe and well tolerated also in this patient population

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*Treatment arms across ASPIRE with different durations combined
PR, pegylated interferon α-2a + ribavirin ; SVR24, HCV RNA <25 IU/mL undetectable 24 weeks after planned end of treatment